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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,888	SPURLOCK ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005 and 03 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-30 and 41-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-30 and 41-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03 December 2004 has been entered.

Response to Amendment

Claims 13-30 have been amended and 41-83 have been added as requested in the paper filed 03 December 2004. Claims 1-5 and 31-40 have been canceled. Claims 13-30 and 41-83 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 03 December 2004 have been fully considered but they are not deemed to be persuasive.

Finality of Previous Office Action

At page 18 of the response filed 03 December 2004, Applicant challenges the finality of the previous Office action. Applicant asserts that the Examiner introduced a new ground of rejection "[w]hen the Examiner argued that an allelic variant is only a naturally-occurring molecule and only a product which occurs in nature" because this is considered "a new basis" for rejecting claims 1-5 under 112/1st paragraph. Applicant's arguments are not persuasive. The grounds of rejection were not changed and the response to Applicant's interpretation of the rejection does not constitute a new ground of rejection, absent evidence to the contrary. See MPEP 706.07(a). Any question as to prematureness of a final rejection should be raised, if at all, while the application is still pending before the primary examiner and is reviewable by petition under 37 CFR 1.181 (See MPEP 1002.02(c)). However, since Applicant has canceled the claims in question and has filed an RCE in the instant application, this argument appears to be moot.

Specification

The disclosure is objected to because of the following informalities:

Applicant has filed an amendment to the specification which includes a new Sequence Listing and changes to the specification based on this new Sequence Listing. The following is a recount of the sequences presented and what they appear to represent:

SEQ ID NO:1 is a nucleic acid sequence of Figure 1A-1D.

SEQ ID NO:2 is a nucleic acid sequence of the entire coding region (Fig. 2).

SEQ ID NO:3 is the entire protein sequence (including signal) (Fig. 2).

SEQ ID NO:4 is the entire protein sequence (including signal) (Fig. 2) –

SEQ ID NO:4 is a DUPLICATE of SEQ ID NO:3

SEQ ID NO:5 is a nucleic acid sequence lacking the signal portion (Fig. 3).

SEQ ID NO:6 is an amino acid sequence lacking the signal portion (Fig. 3).

SEQ ID NO:7 is an amino acid sequence lacking the signal portion (Fig. 3) -

SEQ ID NO:7 is a DUPLICATE of SEQ ID NO:6.

SEQ ID NO:8 is a nucleic acid sequence for human leptin (Fig.4).

SEQ ID NO:9 is a nucleic acid sequence for murine leptin (Fig. 4).

SEQ ID NO:10 is a primer found at page 29 of specification.

SEQ ID NO:11 is a primer found at page 29 of specification.

Based on this information which comes directly from Applicant's paper copy of the Sequence Listing, the amendments to the specification are almost completely erroneous. It is not clear why a new sequence listing was submitted in the instant application to begin with – it's submission has resulted in complete chaos as to what is being claimed and what sequences are represented by what sequence identifier.

Additionallly, it is noted that Figure 1A-1D is a genomic DNA sequence which also includes the various coding portions indicated with amino acids. The description of this Figure indicates that the nucleic acid sequence of SEQ ID NO:2 is found in this Figure – it is not. This is because the sequence of SEQ ID NO:2 is continuous and within Figure 1A-1D, this is not a continuous sequence. It is a matter of form, but the information is not correct and should not be noted as such. Since the "coding" portion and the encoded protein are represented in Figure 2, it is suggested that reference to the coding nucleic acid and encoded protein be mentioned with regard to Figure 2 since

this is technically correct and is the basis for the sequences which are in the Sequence Listing. Applicant is referred to 37 CFR 1.822(e) in MPEP 2423.

Appropriate correction is required.

Claim Objections

Claims 17-18 stand objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for the reasons of record in the previous Office action(s). Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims depend from base claims which have two requirements: 1) the DNA molecule must encode a porcine adipocyte leptin and 2) must hybridize to a specified sequence. The dependent claims 17-18 place size limitations on the DNA of "at least 20" or "at least 50" bases, which is no where near the necessary size of a DNA which will encode a porcine leptin polypeptide, absent evidence to the contrary. Therefore, the claims do not appear to further limit the claims from which they depend.

First it should be noted that in response to the above objection, Applicant refers to passages in the published form of the application and to an issued U.S. Patent, of which the instant application is a CIP. Applicant should always include the page and line number of the instant application for basis of claim language and support. The instant application must contain the support what what is being claimed. Additionally,

the instant application may differ from these other publications and the Examiner is not examining the other publications, but rather, the instant application.

Applicant argues that "the Examiner's characterization of the 'at least about 20 bases' and the "at least about 50 bases" as a "size limitation" is inaccurate" and that the Examiner suggests it is improper to define structural features of the isolated DNA in terms of functional attributes. (see page 21 of the response). From Applicant's statements, it is clear that the Examiner and Applicant are not interpreting "encoding porcine leptin polypeptide" as the same thing. (See new ground of rejection for indefiniteness below).

The specification is directed to "DNA and RNA molecules and their respective allelic variants that encode a porcine adipocyte polypeptide, termed "leptin," or a functional derivative thereof, and the porcine leptin protein itself, or a functional derivative thereof". This language is being interpreted as "leptin" being the full-length molecule having the amino acid sequence of SEQ ID NO:2 or 3. Therefore, reference to a molecule "which encodes a porcine adipocyte polypeptide leptin" would mean that the molecule would encode a protein that would be considered leptin. A fragment of 8 amino acids, while described in the instant specification and supported by the instant specification, is not "leptin"; it is a fragment of leptin. This characterization is supported by Applicant's own specification which states

> The polypeptide of this invention has an amino acid sequence as depicted in FIGS. 1A-1D and 2 (SEQ. ID NO. 1 and SEQ. ID NO. 2), and preferably as depicted in FIG. 3 (SEQ. ID NO. 3 and SEQ. ID NO. 4). Also intended within the scope of the present invention is any polypeptide having at least about 8 amino

> acids present in the above-mentioned sequence. (page 10 of the specification) .... As alternatives to a native purified or recombinant porcine adipocyte polypeptide molecule, functional derivatives of the porcine adipocyte polypeptide may be used. As used herein, the term "functional derivative" refers to any "fragment", "variant", "analog", or "chemical derivative" of the porcine adipocyte polypeptide ...(page 9 of the specification) ... A "fragment" of the porcine adipocyte polypeptide as used herein refers to any subset of the molecule, that is, a shorter polypeptide. (page 9 of the specification)

The fact that the base claim requires the isolated DNA molecule to encode "leptin" means that it must be of sufficient length to encode a protein that would be of sufficient length to be considered "leptin". The fact that the specification separately defines a "fragment" from the molecule which is called "porcine adipocyte polypeptide" further supports this interpretation of "porcine adipocyte polypeptide leptin" as being a polypeptide of SEQ ID NO:2 or 3.

Applicant argues that a person of ordinary skill in the art would know how to use the invention being claimed, however, because this is an objection to the claims for failure to limit, these arguments are not relevant. Applicant additionally argues that use of the term "at least" is not intended to limit the isolated DNA to only those 20 to 50 bases in length. The Examiner did not suggest that the claims were limited to that length, but rather that the claims are directed to embodiments which encompass molecules of this length. And since molecules of this length do not encode "porcine adipocyte polypeptide leptin" as interpreted by the Examiner and supported by Applicant's own disclosure, the instant claims do not further limit the claim from which they depend. Molecules of this length would encode a fragment, and claims of this

nature could be presented as independent claims or they could be presented in a different manner so as to not include the requirement that they encode "porcine adipocyte polypeptide leptin".

The objection to the claims is maintained. (Applicant misstated that a rejection was made based on 37 CFR 1.75(c) – see basis for **objection** above.)

Claims 41, 46-49, 51, 54, 59, 63, 65, 69, 73, and 77 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recited claims and the claims from which they depend all recite language regarding encoding "porcine adipocyte polypeptide leptin" or "porcine leptin polypeptide" or "porcine leptin polypeptide leptin" (see claim76). However, the instant specification only describes a single protein of leptin which has been isolated from pigs, making it porcine leptin (Figure 2 and 3). Specifically, the specification indicates at page 3 "this invention is directed to a porcine adipocyte polypeptide (i.e., the porcine leptin protein)" and uses the terms "porcine adipocyte polypeptide" and "porcine leptin" interchangeably as meaning the same protein throughout the specification (see page 6 for example). Therefore, the further dependent claims which recite that the encoded protein is "porcine leptin" is not further limiting.

Applicant should be advised that these claims could be objected to under 37 CFR 1.75 as being substantial duplicates of the base claims if the base claims are found allowable. When two claims in an application are duplicates or else are so close

in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Since the base claims are not allowable at this time, the objection is not being made.

Claim Rejections - 35 USC § 112

Applicant argues at pages 22-24 that claims 1-5 are allowable. This argument is moot in light of Applicant's cancellation of the claims. If the claims are reinstated, they will be rejected. Applicant argues that the 112/1st paragraph rejection based on "allelic variant" is moot in light of the cancellation of this language from the claims. The rejection is being withdrawn in light of the absence of the language from the claims, however, any argument that the claims are directed to "allelic variants" or reinstatement of the language will be cause for rejection of the claims based on lack of written description of this subject matter for the reasons of record in the previous Office action(s).

The rejections based on 112/2nd paragraph will be addressed first because interpretation of the claims is important for why the claims are rejected under 112/1st paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-30 and 41-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-30, 46-52, 57, 62, 63-83 refer to "a nucleotide sequence of SEQ ID NO:3" (or depend from claims which recite SEQ ID NO:3). Because of the new Sequence Listing which was filed 03 December 2004, SEQ ID NO:3 is now an amino acid sequence. Since an amino acid sequence is not a nucleotide sequence, it is not clear what Applicant is claiming. Correction of the Sequence Listing and/or Specification and/or claims may obviate this ground of rejection.

Claims 13, 19-22, 24-25, 27-28, 62, 68, 81 recite the article "a" in place of "the" when referring to the sequence represented by a sequence identifier. This is indefinite when referring to a single sequence because reference to a specific sequence would require the use of the article "the". The use of "a" implies that there are multiple sequences to chose from or represented by the sequence identifier, which is not the case when referring to a specific sequence as one is when referencing a sequence identifier.

Claims 14, 15, 17, 18, 19, 20, 44, 52, 55, 57, 60, 62, 64, 66, 70, 74, 78, 80, 82 are indefinite for the recitation "at least about" in conjunction with a number of nucleotides which are to hybridize. This recitation is indefinite because the lower limits of what are to be encompassed by the claims is not clear. The instant specification does not indicate what range "at least about" is meant to encompass. Furthermore, "at least" is in direct conflict with "about" since "at least" sets a lower limit to the range, but

"about" changes that limit. Therefore, the claims are indefinite because the metes and bounds of "at least about" cannot be determined.

Claims 13-30 and 41-83 are indefinite for the use of ""porcine adipocyte polypeptide leptin" or "porcine leptin polypeptide" or "porcine leptin polypeptide leptin" (dependent claims are included as well, even if they do not explicitly recite the noted language). These recitations are used separately as well as in conjunction with one another as if to denote a distinction between the molecules which are encoded. However, a fair reading of the instant specification would indicate that the above recitations all refer to the same protein, which is leptin produced in pigs. Only a single protein is disclosed in the instant specification (with and without signal sequence; SEQ ID NO:3 and 6) and there is no disclosure to distinguish one recitation from another. Therefore, the use of these recitations as limitations in the claims is vague and indefinite because the specification discloses that they are the same protein as evidenced by the disclosure at page 6. The metes and bounds of what is being claimed cannot be determined because no differences can be ascertained for the different recitations which appear to mean the same thing.

Claims 13-30 and 41-83 are indefinite for the limitation of "stringent hybridization conditions". The limitation "stringent hybridization conditions" is equivalent to reciting a range without indicating the metes and bounds of the conditions since there is no indication of what conditions are to be encompassed by the claims. The specification does not provide a definition of what conditions are considered "stringent" and the art recognizes a multitude of conditions which could be used and considered "stringent".

Page 10 of the specification makes reference to hybridization that "[I]n order to achieve higher specificity of hybridization, characterized by the absence of hybridization to sequences other than those encoding the polypeptide or a functional derivative thereof, a length of at least about 50 nucleotides is preferred". Based on this language, it would seem that claims that include the limitation of "at least about 20 nucleotides" would be in direct conflict with the limitation that "stringent hybridization conditions" are used. Hybridization conditions are found in the specification in conjunction with Example II, however, the specification does not disclose that these conditions are what is intended by the recitation of "stringent hybridization conditions".

Applicant argues this rejection beginning at page 35 of the response through page 46 of the response. The Declaration under 37 CFR 1.132 filed 03 December 2004 is insufficient to overcome the rejection of claims 13-30 and 41-83 based upon indefiniteness as set forth in the last Office action because: the Declaration and the arguments which accompany it demonstrate that there are a multitude of conditions which the prior art and those skilled in the art recognize as being "stringent hybridization conditions". Varying the length of the probe, the temperature at which the hybridization occurs, the salt concentration at various stages including wash steps and varying denaturing agents can all provide different specificities in hybridization. Without knowing which conditions are intended by the claims, the metes and bounds of those molecules which are encompassed by the claims cannot be determined.

Applicant makes many references to the conditions in Examples II and III, however, limitations from the specification cannot be read into the claims. Applicant

may wish to include the conditions which are exemplified in Examples II and III into the claims in order to avoid the rejection of record. However, in the absence of a true definition in the specification that indicates what conditions are intended by "stringent", the rejection is maintained as it is clearly supported by Applicant's own arguments and the Declaration filed that there are a number of variables involved in hybridization, and therefore, a number of different conditions which would provide for "stringent" hybridization.

Claims 16, 21, 23-24, 26-29, 45, 56, 61, 67, 71, 75, 79 and 83 are directed to nucleic acid molecules (DNA, mRNA) which "hybridizes" to "substantially all" of the bases of a recited sequence. However, these claims are indefinite for the failure to indicate what is intended by the recitation "substantially all".

Applicant argues at pages 31-35 that those skilled in the art will be able to understand with a reasonable degree of accuracy what subject matter is circumscribed by the invention, and therefore, that the recitation "substantially all" is definite. Applicant further argues that the Examiner has issued a patent which includes the recitation "substantially all" as well as citing case law related to indefiniteness.

With regard to patents issued by the Examiner with "substantially all" language; each application is examined on its own merits. The facts surrounding the issued patent are not the same and are not applicable to the instant application. In the instant application, the claims are attempting to define the structure of the isolated nucleic acid molecule by its ability to hybridize to another nucleic acid molecule. Hybridization conditions are influenced by a number of different factors, including probe length. The

longer the probe length and how many bases hybridize to the probe, influences what type of molecules are being isolated. As is pointed out elsewhere in this action, "stringent hybridization conditions" are considered indefinite without more because there are a number of conditions which could be considered "stringent" and dependent on which conditions are used, different nucleic acid molecules will be isolated. Likewise, depending on how many bases hybridize (anywhere between 50% and 100% based on Applicant's explanation at page 33), different types of molecules will be encompassed by the claims. The specification does not define "substantially all" and its use in conjunction with the indefinite "stringent hybridization conditions" clearly does not provide sufficient explanation of the metes and bounds of the claims.

If the claims are amended to include those conditions which are to be considered "stringent" and are limited to those conditions provided in the instant specification, then the use of the recitation "substantially all" may be definite in that context. However, as the claims are currently written, the metes and bounds of what is being claimed is indefinite.

Claims 13-15, 17-20, 25, 30, 41-42, 44, 50, 52, 53, 55, 57,58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first step in determining if a claim meets the enablement requirements of 35 U.S.C. 112, first paragraph, is understanding what is being claimed. The instant claims are directed to nucleic acid molecules which encode a porcine leptin polypeptide, wherein the nucleic acid hybridizes to at least about 20-50 bases of SEQ ID NO:1, 20-50 bases of SEQ ID NO:3, or wherein the nucleic acid molecule is at least 20-50 bases long. It is clear that the instant specification encompasses and intends for fragments of porcine leptin to be encompassed in the scope of the invention. However, the instant specification only describes a single protein which can be called "porcine adipocyte polypeptide leptin" or "porcine leptin polypeptide" or "porcine leptin polypeptide leptin" , and this protein is 166 amino acids in length with the signal sequence and 145 amino acids in length without the signal sequence. The prior art nucleic acid molecules which encode leptin are also described in Figure 4, which encode a leptin of a similar length to that of the disclosed porcine leptin. The specification distinguishes fragments from the "leptin" depicted in Figure 2 at page 7 of the specification; "[a]lso intended within the scope of the present invention is any polypeptide having at least about 8 amino acids present in the above-mentioned sequence." Therefore, the claims are directed to nucleic acid molecules which encode porcine leptin (functional limitation) wherein the nucleic acid molecule hybridizes to at least about 20 (or 50) nucleotides of a disclosed nucleic acid molecule or wherein the isolated nucleic acid molecule is at least about 20 (or 50) bases in length (structural limitation).

First, the art does not recognize a nucleic acid as short as 20-50 nucleotides long that encodes a leptin molecule and the instant specification fails to teach a molecule

meeting this limitation. The specification does teach that a fragment of 20 nucleotides is intended in the scope of the claims, but it does not teach that this length is sufficient for encoding leptin as defined in the instant specification as corresponding to SEQ ID NO:2. Therefore, one of ordinary skill in the art would not find such a length sufficient for encoding a leptin molecule from pigs, absent evidence to the contrary, and the claims are not enabled for such. Next, SEQ ID NO:1 is a genomic sequence with significantly long stretches of non-coding regions. The claims encompass isolated DNA which hybridizes to at least 20 or 50 nucleotides of SEQ ID NO:1, however, the vast majority of the nucleic acid molecules which hybridize (again, no conditions are provided, so the majority of nucleic acids in existence would hybridize under various conditions) to 20 or 50 bases would not meet the functional requirements of the claims, which are to encode a porcine leptin polypeptide. The structure which is given is not sufficient to result in the required function of the claims, and the claims are not enabled.

Applicant argues the rejection at pages 25-30 of the response. However, Applicant's arguments are based on the premise that a nucleic acid molecule of "at least about" 20 bases encodes porcine leptin. For the reasons given above and supported by the disclosure of the instant specification, this is a false premise. Therefore, the rejection is maintained for the reasons of record and for those reasons given above. Applicant may wish to amend the claims to eliminate the functional requirement that the isolated nucleic acid molecule encode porcine leptin, and this may obviate this ground of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-28 and 42-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (U.S. Pat. No. 6,309,853).

The instant specification defines a functional derivative as

> Any "fragment", "variant", "analog", or "chemical derivative" of the porcine adipocyte polypeptide that retains at least a portion of the function of the porcine adipocyte polypeptide which permits its utility in accordance with the present invention. (page 9 of the specification)

The instant claims are directed to isolated nucleic acids which encode porcine leptin or a "functional derivative thereof" or "variant thereof" . The prior art of Friedman et al. (U.S. Pat. No. 6,309,853) disclose nucleic acids which encode human and mouse leptin, which would be considered functional derivatives and/or variants of the disclosed porcine leptin since they encode leptin molecules and would possess similar functional properties as those of the porcine leptin, absent evidence to the contrary. Friedman et al. teach that the leptin gene (or OB) could be isolated from domestic animals using the methods disclosed therein (see column 26, line 53 to column 27, line 49). Friedman et al. specifically mention swine as a domestic animal for which leptin would be useful (see column 48, lines 41-57). Friedman et al. do not specifically disclose an isolated nucleic acid encoding a porcine leptin polypeptide. However, it would have been obvious to

use the nucleic acid of Friedman et al. encoding human or mouse leptin and hybridize it to a porcine cDNA library and isolate a nucleic acid molecule encoding porcine leptin because Friedman et al. teach methods for isolating leptin encoding nucleic acids and also teach that it would be beneficial to administer leptin to swine. It would also have been prima facie obvious to use the nucleic acid of Friedman et al. encoding human or mouse leptin and hybridize it to porcine genomic DNA to isolate the gene encoding porcine leptin because it would have been beneficial to more completely understand the gene structure of porcine leptin. It also would have been prima facie obvious to use the nucleic acid of Friedman et al. encoding human or mouse leptin and hybridize it to porcine mRNA to isolate the mRNA encoding porcine leptin for the benefit of understanding the nature of porcine leptin expression. Therefore, the invention as a whole would have been obvious at the time it was made, absent evidence to the contrary.

Applicant should note that the instant rejection is being made because the claims do not require the specifics of the porcine leptin of the instant specification, and therefore, methods of isolating nucleic acids for leptin using a functional equivalent of porcine leptin encoding DNA encompasses methods using human or murine DNA encoding leptin.

Applicant argues the rejection at pages 46-53 of the response. Applicant's arguments appear to be based on the premise that the porcine leptin of the instant application is functionally different from the human and mouse leptin of the prior art. However, the rejection is not one of anticipation, but rather that the human and mouse

leptin of the prior art meet the limitation of being functional derivatives based on the disclosure of the instant specification at page 9. Because Friedman et al. teach nucleic acid molecules which are "functional derivatives" and "derivatives" of the porcine leptin of the instant application and because Friedman et al. teach that the nucleic acid molecules encoding leptin could be used to isolate nucleic acid molecules encoding leptin from other species, specifically swine, isolated nucleic acid molecules encoding porcine leptin are obvious over the teachings of Friedman et al.

Applicant refers to the Declaration submitted with the response as evidence that human and mouse leptin do not have the exact same activity as porcine leptin, and therefore, are not functional derivatives. However, Applicant is reading limitations into the claims which are not present in the specification as filed or supported by the instant specification as filed. The instant specification only requires retention of "at least a portion of the function of the porcine adipocyte polypeptide", which could mean that the polypeptide only retain antigenicity, for example. Applicant's reliance on the very detailed biological differences between porcine leptin and human/mouse leptin is noted, but is not persuasive to obviate the rejection for the reasons provided above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud